

## Food and Drug Administration, HHS

## § 82.6

82.1708 D&C Yellow No. 8.  
82.1710 D&C Yellow No. 10.

### Subpart D—Externally Applied Drugs and Cosmetics

82.2050 General.  
82.2051 Lakes (Ext. D&C).  
82.2707a Ext. D&C Yellow No. 7.

AUTHORITY: 21 U.S.C. 371, 379e, 379e note.

SOURCE: 42 FR 15669, Mar. 22, 1977, unless otherwise noted.

### Subpart A—General Provisions

#### § 82.3 Definitions.

For the purposes of this part:

(a)–(f) [Reserved]

(g) The term *alumina* means a suspension in water of precipitated aluminum hydroxide.

(h) The term *blanc fixe* means a suspension in water of precipitated barium sulfate.

(i) The term *gloss white* means a suspension in water of co-precipitated aluminum hydroxide and barium sulfate.

(j) The term *mixed oxides* means the sum of the quantities of aluminum, iron, calcium, and magnesium (in whatever combination they may exist in a coal-tar color) calculated as aluminum trioxide, ferric oxide, calcium oxide, and magnesium oxide.

(k)–(m) [Reserved]

(n) The term *externally applied drugs and cosmetics* means drugs and cosmetics which are applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane.

(o)–(p) [Reserved]

(q) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable also to such terms when used in this part.

#### § 82.5 General specifications for straight colors.

No batch of a straight color listed in subpart B, C, or D shall be certified under this part unless:

(a) It is free from all impurities (other than those named in paragraph (b) of this section or in the specifications set forth in such paragraph for such color) to the extent that such impurities can be avoided by good manufacturing practice.

(b) It conforms to the following specifications:

(1) In the case of a straight color listed in subpart B:

(i) Lead (as Pb), not more than 0.001 percent.

(ii) Arsenic (as As<sub>2</sub>O<sub>3</sub>), not more than 0.00014 percent.

(iii) Heavy metals (except Pb and As) (by precipitation as sulfides), not more than trace.

(2) In the case of a straight color listed in subpart C or D:

(i) Lead (as Pb), not more than 0.002 percent.

(ii) Arsenic (as As<sub>2</sub>O<sub>3</sub>), not more than 0.0002 percent.

(iii) Heavy metals (except Pb and As) (by precipitation as sulfides), not more than 0.003 percent.

(3) In the case of a straight color which contains a barium salt listed in subpart C or D—soluble barium (in dilute HCl) (as BaCl<sub>2</sub>), not more than 0.05 percent.

#### § 82.6 Certifiable mixtures.

(a) A batch of a mixture which contains no straight color listed in subpart C or D may be certified for use in food, drugs and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture;

(2) Each diluent in such batch of mixture is harmless and suitable for use therein; and

(3) No diluent (except resins, natural gum, pectin and, in the case of mixtures which are aqueous solutions or aqueous pastes, sodium benzoate in a quantity of not more than 1/10 of 1 percent) in such mixture is a nonnutritive substance, unless such mixture is for external application to shell eggs, or for use in coloring a food specified in the requests for certification of such batch submitted in accordance with § 80.21 of this chapter, and such diluent, in the usual process of manufacturing such food, is removed and does not become a component of such food.

(b) A batch of a mixture which contains no straight color listed in subpart